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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/726,134	12/01/2003	Gary D. Niehaus	200047.150	6114
21324	7590	06/30/2004	EXAMINER	
HAHN LOESER & PARKS, LLP TWIN OAKS ESTATE 1225 W. MARKET STREET AKRON, OH 44313			DO, PENSEE T	
			ART UNIT	PAPER NUMBER
			1641	

DATE MAILED: 06/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/726,134	Applicant(s) NIEHAUS ET AL.	
	Examiner Pensee T. Do	Art Unit 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 May 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3, 4, 7, 17, 18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 3 recites that the receptor is attached to i) the surface of said substrate and ii) the pores of the porous substrate. How many substrates are there? How can the receptor be attached to two different substrate? The same confusion is found in claim 4, e.g. the receptors are attached to and randomly distributed on the surface and within the pores of said spherical substrate. How is one receptor attached to the surface of one substrate and at the same time attached to the pores of another porous substrate?

In claim 3, "the pores" also lacks antecedent basis.

Claim 4 also lacks antecedent basis for "said porous substantially spherical substrate". The substrate has not been defined as "spherical" in the previous claim.

Claim 17 recites "a method of claim 15" which is indefinite and fails to further limit the claim 15 since claim 15 is a device claim.

Claim 18 lacks a correlation step. The preamble recites a method for detecting ligands. However, there is no step that correlates such detection in the

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body of the claim. Claim 18 is unclear of the relationship between the amplification mechanism and the receptor.

Claim 19 is indefinite for reciting "interfaced" because it is unclear of what interfaced means in the last part of the claim. Claim 19 is also unclear of the relationship between the amplification mechanism and the receptor.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-6, 9-11, 15-17 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 5 of U.S. Patent No. 6,171,802 in view of Holmgren et al. (US 5,681,571).

Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 5 of patent '802 and the current invention are drawn to the same device for detecting ligands comprising multiple wells, the receptor is attached to the wells, wherein the receptor binds to the ligand and form a ligand-receptor complex which produces a signal; and an amplification

mechanism, wherein said amplification mechanism is a lyotropic liquid crystalline material coupled to the receptor and said amplification mechanism amplifies said signal upon the formation of the ligand-receptor complex.

However, Patent '802 fails to teach the substrate which is made of polymers, such as polystyrene. Instead, Patent '802 teaches wells as substrate and the receptors are randomly distributed on those wells.

Holmgren teaches immunological assays using solid phase such as polystyrene microwells coated with receptor. (see col. 12, lines 38-44).

It would have obvious to one of ordinary skills in the art to use polystyrene microwell as a substrate as taught by Holmgren in the method of patent '802 since receptors can attach to those wells and must be randomly distributed on those wells. When the receptors are coated on the wells, coating must be done through physical or chemical attachment such as hydrophobic interactions and van der Waals interactions or covalent bonding respectively. Thus, one of ordinary skills in the art would be motivated to arrive at the present invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1-6, 8-17, 19 are rejected under 35 U.S.C. 102(e) as being anticipated by Anderson (US 6,482,517).

Anderson teaches a spherical particle coated with nonlamellar crystalline material includes an internal core having at least one nano-structured liquid crystalline material – lyotropic or thermotropic liquid phase and an external coating of receptor protein (see figure 2). Although the utility of the crystalline material is not defined as to amplifying signal, Anderson still inherently teaches it because if Anderson's particles have the same components as those of the present invention, then when Anderson's particles are applied to the same utility as that of the present invention, they would perform the same functions. Such particle is used in clinical/diagnostic assays. For the external coating, the nonlamellar crystalline material can be an organic compound, an inorganic compound, and minerals, metal such as gold. The structure of the coating material can be non-porous or porous. The receptor protein is coated on the external coating. The nanostructured liquid phase material can be formed from a block copolymer such as polystyrene, polysulfones, polyamides, etc. (see col. 25,

lines 15-20; col. 26, line 50-col. 27, line 35). The receptor protein is attached to the external coating through chemical attachment or physical attachment. It is inherent that chemical attachment is done through covalent binding and physical attachment is carried out by hydrophobic interactions and van der Waals interactions (see col. 3, line 25-col. 4, line 12; col. 30, lines 20-24; col. 32, line 54-col. 33, line 5; col. 35, lines 56-59; examples 27 & 28).

Claims 1-6, 8-11, 15-17 are rejected under 35 U.S.C. 102(e) as being anticipated by Abbott (US 6,284,197).

Abbott teaches a device and method for detecting analytes. The device comprises a substrate having a surface, the surface comprises a recognition moiety; a mesogenic layer/ liquid crystals oriented on the surface; and an interface between the mesogenic layer and a member selected from the group consisting of gases, liquids, solid and combination thereof. The interaction of the molecules with surface can be converted into an easily detected optical output. Abbott also teaches a method for detecting analytes comprising contacting with the analyte a recognition moiety for the analyte, wherein the contacting causes at least a portion of a plurality of mesogens/liquid crystals proximate to the recognition moiety to detectably switch from a first orientation to a second orientation upon contacting the analyte with the recognition moiety; and detecting the second configuration of the at least a portion of the plurality of mesogens, whereby the analyte is detected. The liquid crystals are used to amplify and transduce into an optical signal. The interaction of the liquid crystals with a surface can be converted into an easily detected optical output. Liquid crystal

phase can be thermotropic or lyotropic. The recognition moieties are attached to the substrate surface through covalent bonding chemical interaction, ionic bonding, hydrophobic, van der Waals interactions, chemisorption, physisorption and combination thereof. The substrate surface can be made surface-active by attaching to the surface a spacer that has surfactant properties. Spacers serve to distant the recognition moiety from the substrate or self-assembled monolayer. Recognition moiety refers to molecules that are attached to either functionalized spacer arms or functionalized self-assembled monolayer components. The recognition moieties interact with analytes. The substrates can be inorganic crystals, inorganic glasses, metals such as gold, silver, platinum, palladium, nickel and copper, organic polymers such as polyethylene, polysobutene, polyacrylics, polystyrene, polyesters, polysulfones, etc. and combination thereof. Mesogenic layers have been anchored on curved surfaces. The local state of the mesogenic layer is similar to that of mesogenic layers anchored on a planar surface and properties of the mesogenic layer are not dominated by elastic energies caused by curvature. curvature. The receptor can be a monoclonal antibody.(col. 6, line 1-col. 6, line 30, col. 13, lines 12-17,. col. 14, lines 34-43, col. 35, lines 40-46).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which

said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 12-14 and 18 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Abbott et al. (US 6,284,197) further in view of Tarcha et al. (US 5,252,459).

Abbott has been discussed above.

However, Abbott fails to teach that the shape of the substrate is spherical.

Tarcha teaches assay method using solid phase/substrate materials such as chromatographic, bibulous, porous capillary material, fiberglass, cellulose or nylon pad, silicon particles, porous gels such as silica gel, agarose, dextran, polyacrylamide beads, polystyrene beads, magnetic beads, etc. The method of attachment the specific binding member to the solid phase is by adsorption or covalent binding. (see col. 4, line 50-col. 5, line 17).

It would have been obvious to one of ordinary skills in the art to configure the shape of the substrate taught by Abbott into spherical shaped beads/particles as spherical shaped beads are well known in the art as solid phase supported by the teachings of Tarcha. Furthermore, since Abbott teaches that the properties of the mesogenic layer being anchored on a curved surface are the same as compared to those of the mesogenic layer when anchored on a planar surface, one of ordinary skills in the art would find it obvious to use substrate with a curved shape such as beads or particles.

Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson (US 6,482,517) or Abbott (6,284,197) in view of Sahouani et al. (US 6,524,665).

Anderson and Abbott have been discussed above.

However, Anderson and Abbott fail to teach that the liquid crystalline material is chromonic.

Sahouani teaches an alignment structure useful in a liquid crystal display device comprising a substrate having disposed thereon a film of a lyotropic nematic or chromonic liquid crystalline material. Figure 1 in shows a scanning electron microscopic image of the surface of a polymeric substrate shear coated with a layer of compound A. (see col. 3, lines 5-11; col. 4, lines 65-69; col. 5, lines 1-4).

It would have been obvious to one of ordinary skills in the art to use chromonics as lyotropic liquid crystalline material in the method and device of Anderson or Abbott because chromonic molecules show a self-organized surface structure that easily and uniformly orient liquid crystals or non-liquid crystal coatings in planar configuration. Thus, these self-organized surface structures can also easily and uniformly orient the receptors when become attached thereto. Such uniform orientation of the receptors would be an advantage because that way all receptors can be exposed to the ligands of interest and thus the signal would be accurate.


Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pensee T. Do whose telephone number is 571-272-0819. The examiner can normally be reached on Monday-Friday, 7:00-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Pensee T. Do
Patent Examiner
June 22, 2004


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6/22/04